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In re Application of	:
Martin Gleave et al	:
Serial No.: 10/605,498	:
Filed: 02 October 2003	:
Attorney Docket No.: UBC.P-031	:

This letter is in response to the Petition under 37 C.F.R. 1.144, filed 29 January 2006 requesting review of the Ex parte Quayle action mailed 30 November 2005 and the restriction requirement requiring election of a single sequence among SEQ ID NOS.: 1 - 93 as originally set forth in the communication mailed to applicants on 23 March 2005.

BACKGROUND

This application was filed on October 2, 2003, under 35 U.S.C. 111, and contained claims 1-24. On March 23, 2005 the examiner mailed to applicants a restriction requirement wherein the 24 claims were divided into two groups--methods of treating cancer (claims 1 - 13) and pharmaceutical compositions (claims 14 - 24). In this same communication the examiner required further restriction among SEQ ID NOS. 1 - 90 because these sequences represented an improper Markush group since unity of invention was lacking.

On 20 April 2005 applicants responded to the restriction requirement by electing without traverse the pharmaceutical compositions of Group II, claims 14 - 24. New claims 25 - 28 were also added at this time. Applicants elected SEQ ID NO. 82 for initial examination. No traversal of the requirement was set forth.

On 12 May 2005 the examiner mailed to applicants a first Action on the merits in which claims 14 - 17, 19 and 25 - 28 were all rejected. Claims 14 - 17 and 25 and 26 were rejected under 35 U.S.C. 112, first paragraph, for lack of adequate written description and claims 14 - 17, 19, and

25 - 28 were also rejected under 35 U.S.C. 102 and 103(a) as being anticipated and/or obvious over various references.

Applicants replied on 11 August 2005, amending claim 14 and responding to the rejections appropriately

On 07 September 2005 the examiner mailed to applicants a FINAL rejection in which all pending claims 14 - 17, 19, and 25 - 28 were rejected over prior art under 35 U.S.C. 102(b) and/or 103(a). The restriction requirement became final at this time also.

On 17 October 2005 applicants and the examiner held a telephone interview and discussed amending the claims to recite "**the** consecutive series" rather than "**a** consecutive series" as well as a stringency requirement in order to overcome the 102 rejections of record.

On 26 October 2005 applicants filed an After Final amendment in which claim 14 was amended to be a Markush group of SEQ ID NOS. 1 - 90. New claims 29 - 43 were also added at this time.

On 10 November 2005 the examiner mailed to applicants an Advisory Action wherein it was noted that applicants had amended claims to recite sequences that were not previously examined. It was noted that applicants had previously elected antisense SEQ ID NO. 82. The examiner further noted that if this amendment were entered, the additional sequences would be subject to a restriction requirement.

On 30 November 2005 in a telephone interview with the examiner, applicants expressed their position that the amendment filed 26 October 2005 should be entered because these sequences were present in the original claims. The examiner agreed to enter the amendment filed 26 October 2005 but also indicated that these reintroduced sequences would be withdrawn from examination because they are directed to non-elected inventions.

On 30 November 2005 the examiner mailed to applicants an *Ex parte Quayle* action indicating that the application was in condition for allowance except for formal matters. A complete reply to this action was required to include cancellation of the non-elected claims or other appropriate action (37 C.F.R. 1.144).

On 29 January 2006 applicants filed a second After Final amendment to correct minor typographical errors and requested reconsideration and further examination for all pending claims.

On 29 January 2006 applicants also filed this Petition under 37 C.F.R. 1.144 requesting review of the restriction requirement and the requirement of election of a single sequence for examination as set forth in the communication mailed 23 March 2005.

DISCUSSION

The above file history has been thoroughly reviewed and considered.

It is important to note that applicants did not traverse any part of the restriction requirement mailed 23 March 2005. Applicants were under the impression that the election of SEQ ID NO. 82 was effectively an election of species requirement rather than a true restriction requirement. Applicants state, "This election was made without traverse with the understanding that it was a species-type election, and that the generic claims and other species would be recombined and considered in the absence of prior art." However, the examiner clearly stated that the she was requiring an additional restriction among the 90 SEQ ID NOS because the listing of SEQ ID NOS. was considered an improper Markush group.

Applicants' argument has been fully considered but is not deemed persuasive.
Although each of the 90 antisense sequences target and modulate the expression of the same gene, the instant antisense sequences are considered to be unrelated to each other, since each antisense sequence has a unique nucleotide sequence, each antisense targets a different and specific region of hsp27, and each antisense, upon binding to hsp27, functionally modulates the expression of the gene to a different degree. Furthermore, a search of more than one of the antisense sequences claimed presents an undue burden on the Office due to the complex nature of the search and corresponding examination of more than one of the claimed antisense sequences.

Applicants point out that during prosecution the examiner has considered generic claims to hsp27 oligonucleotide antisense generally and to any antisense targeted to hsp27, i.e., SEQ ID NO. 91. The examiner has also considered the specific sequence of SEQ ID NO. 82. Applicants further argue that the examiner has not identified a single reference which discloses an antisense oligonucleotide targeted to hsp27, thus suggesting the allowability of the generic claim to the treatment of cancer with any antisense oligonucleotide to SEQ ID NO. 91. Therefore, applicants cannot understand how there could be an undue burden on the examiner to search and examine methods for treating cancer using any of the 90 SEQ ID NOS. in the claims.

Applicants' argument has been fully considered and is deemed persuasive. Since claim 14 was originally a generic or linking claim, and if this generic or linking is allowable, then the claims depending from said the linking claim should be rejoined and fully examined.

Finally, applicants emphasize that the restriction of the method claims to a single SEQ ID NOS. appears arbitrary because it appears that the examiner has not even considered that SEQ ID NOS. 81 and 82 differ only by a single base. Similarly, SEQ ID NOS. 79 and 80 also differ by only a single base. Applicants' argument has been fully considered and is deemed persuasive in part. Since SEQ ID NO. 81 is identical to SEQ ID NO. 82 except for one extra base, the search of SEQ ID NO. 82 should also have been adequate as a search for SEQ ID NO. 81 since they are 95% identical. The examiner's sequence search indicates that there was no sequence found that was more than 65% identical to SEQ ID NO. 82. Therefore, this would lead to the conclusion that SEQ ID NO. 81 is allowable over the prior art.

DECISION

For the above reasons, the Petition, requesting withdrawal of the restriction requirement among SEQ ID NOS 1 - 90 is **GRANTED-IN-PART**.

This case will be returned to the examiner for examination of compositions comprising SEQ ID NO. 81 since this differs from the elected SEQ ID NO. 82 by a single base and because the search of SEQ ID NO. 82 should have been an adequate search for SEQ ID NO. 81 as well. In addition, the examiner will permit entry of the amendment adding back a generic or linking claim as in the original claim 14. If the examiner finds this generic or linking claim to be allowable, then all of the claims depending from this generic or linking claims will, of necessity, be rejoined and examined fully.

Any request for reconsideration of this decision must be filed within two (2) months of the mailing date of this decision in order to be considered timely.

Should there by any questions regarding this decision, please contact Special Program Examiner, William R. Dixon, Jr. by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number, 571-273-8300.

George C. Elliott
Director, Technology Center 1600